JUL 1 2 2000

K001587

Special 510(k) Device Modification:
19 Ga Plastic Reinforced Epidural Catheter

P.O. Box 12888
Reading, PA 19612

ARROW INTERNATIONAL

Research/Engineering
2400 Bernville Road
Reading, PA 19605

(610) 378-0131
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SECTION 5 – 510 (K) SUMMARY

A. Submitter's information

Name

Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605

Contact Person:

Tomas D. Nickel
VP, RA/QA
Phone: 610-478-3137
Fax: 610-478-3172
E-mail: Tom.Nickel@Arrowintl.com

Date summary prepared

May 19, 2000

B. Device names

Trade Name

19 Ga Plastic Reinforced Epidural Catheter

Common Name

Epidural Catheter

Classification Name

Kit, Conduction, Anesthetic, CAZ, per 21 CFR 868.5140

C. Legally marketed device to which the device is substantially equivalent

The predicate device is Arrow's Continuous Epidural Anesthesia Kit with Polyurethane Catheter, K884552.

D. Description of device

The 19 Ga Plastic Reinforced Epidural Catheter is a fiber-reinforced, single lumen, multi-layered catheter with removable Tuohy-Borst hub. The reinforcing fibers are four individual leads one of which contains a radiopacifier. Centimeter markings are printed on the catheter to allow the physician to identify the depth of the catheter during the insertion procedure.

E. Intended use of the device

The Arrow epidural catheter permits access to the epidural space.

F. Technological characteristics

There are no changes in technological characteristics from the predicate device.

G. Assessment of non-clinical performance data

Testing was performed to confirm material strength and flexibility, flow rates, and compatibility with the removable hub. All acceptance criteria were met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2000

Mr. Thomas D. Nickel
Arrow International, Inc.
2400 Bernville Road
Reading, PA 19605

Re: K001587
19 Ga. Plastic-Reinforced Epidural Catheters
Regulatory Class: II (two)
Product Code: CAZ
Dated: June 9, 2000
Received: June 12, 2000

Dear Mr. Nickel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K001587

Device Name: 19 Ga Plastic Reinforced Epidural Catheter

Indications for Use: The Arrow epidural catheter permits access to the epidural space for the administration of epidural anesthetic. This epidural catheter is intended for use up to 72 hours.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001587